DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 23, 2015

Getinge (Suzhou) Co., Ltd
% David Moynham
Senior Regulatory Affairs Engineer
Arjohuntleigh AB
35 Portmanmoor Road
Cardiff, CF24 5HN GB

Re: K143438
Trade/Device Name: Flowtron ACS900
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: May 29, 2015
Received: June 1, 2015

Dear Mr. Moynham,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

ARJOHUNTLEIGH
GETINGE GROUP

**510(k) Number:** K143438

**Device Name:** **Flowtron ACS900**

**Indications for Use:**

To help prevent Deep Vein Thrombosis (DVT)

| Prescription Use | | Over-The-Counter Use |
|---|---|---|
| **YES** | AND/OR | **NO** |
| (Part 21 CFR 801 Subpart D) | | (Part 21 CFR 801 Subpart C) |

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

ARJOHUNTLEIGH
GETINGE GROUP

# 510K Summary
# Flowtron ACS900

Name & Address: Getinge (Suzhou) Co., Ltd
No. 158 Fangzhou Road, Suzhou, 215024
Jiangsu
China

Telephone: +(44) 2920 485885

Fax: +(44) 2920 492520

Prepared: 26 November 2014

Contact: David Moynham – Regulatory Affairs Engineer

Device Name: Flowtron ACS900

Common Name: Compressible Limb Sleeve

Classification:

| Class | Product Code | Classification Regulation |
|---|---|---|
| II | JOW | 870.5800 |

Classification Name: Sleeve, Limb, Compressible

Predicate Device: Flowtron ACS800 pump (K133119) cleared 28 Feb 2014, manufactured by ArjoHuntleigh AB.

This predicate has not been subject to a design-related recall.

Indications for Use: To help prevent Deep Vein Thrombosis (DVT)

Description :

The Flowtron ACS900 is a pneumatic pump that supplies compressed air to inflate compression garments that are attached to patient's limbs.

It is designed to work with the ArjoHuntleigh ranges of DVT calf/thigh compression garments, Foot compression garments and Tri Pulse calf/thigh compression garments.

The pump automatically senses the type of compression garment connected and adjusts the pressure/time cycle accordingly.

Each garment is compressed alternately, applying pressure to the patient's limb, to help prevent deep vein thrombosis.

Models:

| Model REF | Device | Features |
|---|---|---|
| 526000-01 | Flowtron ACS900 | AC powered pump |
| 526000-02 | Flowtron ACS900 | AC powered pump with longer length connection tubes |

Substantial Equivalence:

Flowtron ACS900 is substantially equivalent to cleared device Flowtron ACS800 +Tri Pulse pump (K133119). The Flowtron ACS900 pump has the same compression pressure / time profiles for the DVT. Foot and Tri Pulse Garments.

Testing to demonstrate equivalence included:

| Testing conducted | Result |
|---|---|
| Full validation of pump software / hardware functionality, including<br>- Garment detection<br>- Therapy delivery | Passed |
| Performance testing garments – Pressure cyclic test.<br>with Tri Pulse garments<br>with Foot garments<br>with DVT garments | Passed |
| Electrical Testing to Standard AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012 | Complies with Standard |
| EMC testing to Standard IEC 60601-1-2, 2007 | Complies with Standard |
| Environmental Stability testing.<br>-Storage / Distribution Test.<br>-Operational Temperature /Humidity Test. | Passed |

Technologies Summary:

The Flowtron ACS900 contains an air compressor, air distribution valve and a microprocessor based control system, housed in a durable plastic casing.

The control system sets and monitors the air pressure cycle applied to the compression garments. It also monitors for faults caused by incorrect user set-up, compression garment failures and pump system problems.

Automatic compression garment recognition is achieved by sensing a specific value inductor. The value inductor is built into the compression garment hose connector.

Conclusion:

The data detailed within submission including that drawn from the nonclinical tests demonstrate that the device is as safe and effective as the legally marketed predicate devices.